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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/848,225

05/04/2001

Kenichiro Shiroyama

Q64175

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05/16/2008

SUGHRUE-265550

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

05/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/848,225	Applicant(s) SHIROYAMA ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and response all dated 1-25-08 is acknowledged.

Claims 1-6 and 8-11 have been canceled. Claims 7 and 12-20 are pending.

Response to Arguments

In response to the amendment of claim 7, where R1 now represents only saturated hydrocarbons, the following rejection of record has been withdrawn:

Claims 7 and 12-14 are rejected, under 35 U.S.C. 103 (a) as being unpatentable over US 5,294,444 in view of US 5,641,495 to Jokura et al (Jokura).

Applicant's arguments filed 1-25-08 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,294,444 in view of US 6,355,232 to Kaneko et al (Kaneko).

Nakamura teaches a transparent or semi-transparent cosmetic composition comprising an amphipathic lipid, nonionic surfactant, ionic surfactant and an aqueous medium (abstract, col. 2, lines 1-18). The amphipathic lipids of the Nakamura includes ceramides such as those described by formula I. Nakamura teaches the non-ionic surfactant of instant claim 13 (col. 3, lines 1-5 & tables 2 and 3), cholesterol and fatty acids (table 2). The amounts of ceramides, non-ionic surfactants, fatty acids and cholesterol in the composition taught by Nakamura are within the instant claimed ratios

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(table 2). With respect to the claimed method step of mixing lipid composition while heating at 80 -120 degrees C and heating water at 80 to 100 degrees C, Nakamura teaches that the components of table 3 were mixed and melted at a temperature of 85-90 degrees C (within the heating temperature of instant claims), followed by addition of hot water (Col. 4, lines 51-55). While Nakamura fails to state the specific temperature of water, absent evidence to the contrary, the term "hot water" includes boiling water, which is 100 degrees C or water as hot as 80 C. Nakamura also teaches that the compositions do not irritate the skin, as claimed (col. 1, lines 65-68).

Nakamura teaches ceramides, glycerocermides and ceramide derivatives, but does not teach the ceramides having the structural formula of instant claims.

Nakamura fails to teach the claimed optically active compounds.

Kaneko teach skin protective compositions comprising erythro (2S, 3R) type of ceramides having the structural formula I –VI (col. 2, lines 15 through col. 3, lines 57). In particular, the ceramides of structural formula I meets the claimed structure II of claim 15. Kaneko also suggests a combination of amphipathic surfactants such as fatty acids, fatty alcohols etc., and cholesterol or a phytosterol, in the composition (col. 3, lines 58 through col. 4, lines 28). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to replace the ceramides of Nakamura, with the optically active ceramides of Kaneko because Kaneko teaches that the optically active ceramides exert remarkable water-barrier functions in skin protection compositions, as opposed to the racemates and significantly higher water holding capacity than racemates and pseudoceramides (col. 1, lines 59-67 and col. 8, lines 10-

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15). Thus, a skilled artisan would have expected that the ceramides of Kaneko to function better than the ceramides or pseudoceramides of Nakamura. While Kaneko fails to teach the specific ceramides of claims 18-20, in the absence of establishing an unexpected result with respect to the specific active ceramides taught by Kaneko, one of an ordinary skill in the art at the time of the instant invention was made would understand from the teachings of Kaneko that the 2S, 3R type of ceramides (optically active) are significantly more efficient in their skin moisturizing effect than the racemates and pseudoceramides because Kaneko teaches that the water restraining capacity of optically active ceramides is higher than the other ceramides (col. 8, lines 18-56).

RESPONSE: With respect to Nakamura and Kaneko, it is argued that the word “ceramide” in Nakamura does not describe as what compounds are present and not exemplified and hence the reference only describes pseudoceramides. It is argued that the pseudoceramides of Nakamura are different from the ceramide of instant; a skilled artisan would not be able to predict which compound would have a better function. Applicants’ arguments are not persuasive because Nakamura teaches that the amphipathic lipids include ceramides, glyceroceramides, phospholipids etc., but prefers the compounds of formula II. However, the teachings of the prior art are not limited to preferred embodiments and should be an ordinary meaning and interpreted in a broader scope. Accordingly, a skilled artisan would have understood that the term ceramides of Nakamura includes the ceramides of Kaneko and therefore the motivation to include the

ceramides of Kaneko in the teachings of Nakamura with an expectation to achieve better skin moisturization properties and water restraining capacity in the skin.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
Art Unit 1611
May 12, 2008